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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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| ACUITAS THERAPEUTICS INC.,<br><br>Plaintiffs,<br><br>v.<br><br>GENEVANT SCIENCES GMBH, AND ARBUTUS BIOPHARMA CORP.<br><br>Defendants. | ) | Civil Action No. _____<br><br>**COMPLAINT FOR DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY**<br><br>**Jury Trial Demanded** |

Acuitas Therapeutics Inc. ("Acuitas"), for its Complaint against Genevant Sciences GmbH ("Genevant") and Arbutus Biopharma Corp. ("Arbutus") (collectively, "Defendants"), alleges as follows:

## NATURE OF THE ACTION

1. COVID-19 presented the worst public-health crisis in a century. Three years later, however, the pandemic is over. That is in large part due to the amazing success story of the mRNA vaccines against the virus that causes COVID-19. Those vaccines exist only because of decades of hard work and ingenuity by Acuitas and others to develop the technology that allowed the rapid development of a vaccine to combat the pandemic.

2. As the pandemic receded, however, litigation proliferated regarding who invented various components of the mRNA vaccines. Despite not having invented or produced any COVID-19 vaccine of their own (or any mRNA vaccine for any virus), Arbutus and Genevant threatened Pfizer and BioNTech (which market an mRNA vaccine for COVID-19, COMIRNATY®) with patent infringement. Acuitas invented and provides an essential component used in COMIRNATY®, a lipid nanoparticle ("LNP") that encapsulates the mRNA payload for delivery, and its constituent lipids. This action arises out of Defendants' threats to sue, and suit against, Pfizer and BioNTech, based in part on their use of Acuitas's LNP and lipids.

## THE PROCEDURAL POSTURE

3. This is the second time Acuitas has had to seek a declaratory judgment against Arbutus and Genevant. Acuitas first sued Arbutus and Genevant on March 18, 2022, in the Southern District of New York, seeking a declaratory judgment that Arbutus's patents are invalid and not infringed by COMIRNATY®, after Arbutus and Genevant sent patent-infringement threat letters to Pfizer and BioNTech. *See Acuitas Therapeutics Inc. v. Genevant Scis. GmbH*, Case No. 22-cv-02229-MKV (S.D.N.Y. Mar. 18, 2022) (the "New York Action"). Arbutus and Genevant moved to dismiss the New York Action, arguing that a declaratory-judgment action by Acuitas was unnecessary because Arbutus and Genevant had not, in fact, threatened Pfizer or BioNTech with patent infringement, and might well reach an out-of-court agreement with them.

4. That was not accurate. While Arbutus and Genevant's motion to dismiss Acuitas's New York Action was pending, Arbutus and Genevant did exactly what they implied to the New York Court they had no intention of doing: On April 3, 2023, they sued Pfizer and BioNTech for patent infringement. But rather than doing so in the Southern District of New York, where Acuitas's case was pending, they sued in this Court. *See Arbutus Biopharma Corp. et al v. Pfizer Inc. et al.*, No. 3:23-cv-01876-ZNQ (D.N.J.) ("Arbutus's New Jersey Action"). Arbutus and Genevant explicitly identified Acuitas's lipids and LNP, while studiously not using the word "Acuitas" in their complaint. In answering the complaint in Arbutus's New Jersey Action, Pfizer and BioNTech raised as a defense that Arbutus and Genevant had failed to name or join Acuitas as a "required party." *Arbutus Biopharma Corp. v. Pfizer Inc.*, No. 2:23-cv-01876-ZNQ (D.N.J.) (ECF 17, Fifth Affirmative Defense).

5. Acuitas's declaratory-judgment claim against Arbutus and Genevant being heard in the same Court in which Arbutus's and Genevant's claims against Pfizer and BioNTech are heard will conserve judicial resources and help ensure consistent outcomes.

6. The claims are legally distinct. Acuitas's business model is to develop LNP technology and license it to partners who will use the technology to develop mRNA-based vaccines for pathogens far beyond COVID-19. It is public, for example, that Acuitas is partnering with companies other than Pfizer and BioNTech to investigate therapies directed at a broad range of indications and applications. It is vital to Acuitas's business that its partners and prospective partners can use the licensed Acuitas LNP technology free and clear of interference by threats of suit arising from third party patents. Instead, customers and potential customers of Acuitas must now contend with the risk of avaricious litigation by Arbutus and Genevant, who have demonstrated their willingness to sue Acuitas's customers that use Acuitas LNP technology,

despite the fact that Arbutus and Genevant did not invent and had nothing to do with the success of Acuitas's lipids or vaccines that use them. That threat to other customers and potential customers, and thus the threat to Acuitas itself, would remain even if Arbutus and Genevant were to resolve their dispute with Pfizer and BioNTech. While Acuitas contends that Arbutus and Genevant's claims of infringement are baseless and that their patents are invalid, without a declaratory judgment so holding, Acuitas faces (i) uncertainty with respect to the use of its technology free from the threat of patent infringement, (ii) the possibility of liability under 35 U.S.C. § 271(b) for inducing its customers' infringement or under § 271(c) for contributing to it, or (iii) the possibility of indemnity obligations to its customers under their contracts.

7. There are, however, substantial overlapping legal and factual issues between Arbutus's New Jersey Action and Acuitas's declaratory-judgment claims. Acuitas thus suggested to Arbutus and Genevant that they consent to transfer the New York Action to this Court. Arbutus and Genevant refused. But on August 1, this Tuesday, they wrote to the New York Court to assert—without mentioning their refusal to transfer Acuitas's New York Action to this Court—that Arbutus's New Jersey Action "is uniquely suited to resolve the controversy between Pfizer," BioNTech, and the Defendants. In that letter, Arbutus and Genevant argued that the New York Court should decide their pending motion to dismiss in part because Pfizer and BioNTech did not move "to dismiss" Arbutus's New Jersey Action "on the basis that Acuitas is a necessary party," and that "[t]he closest Pfizer and BioNTech have come" to doing so "is an affirmative defense that states, in its entirety, 'Plaintiffs' Complaint improperly failed to name or join Acuitas Therapeutics, Inc.'" That is not accurate. While Pfizer and BioNTech's Answer and Counterclaims do contain that sentence, it is not the entirety of that defense: The defense is entitled "FAILURE TO JOIN A REQUIRED PARTY." *Arbutus Biopharma Corp. v. Pfizer Inc.*, No.

2:23-cv-01876-ZNQ (D.N.J.) (ECF 17, Fifth Affirmative Defense). And Pfizer and BioNTech included an entire section entitled "BIONTECH'S RELATIONSHIP WITH ACUITAS." *Id*. at ¶¶ 31–34. That Arbutus and Genevant mischaracterize Pfizer and BioNTech's allegations about Acuitas confirms that Arbutus and Genevant recognize the interrelationship between Acuitas's claims and Arbutus's New Jersey Action.

8. Accordingly, Acuitas is withdrawing its New York Action without prejudice, and is filing this declaratory-judgment action in this Court. Acuitas will designate this case as related to Arbutus's New Jersey Action, and is open to working with counsel for all parties in that action to coordinate discovery and case schedules. Acuitas has independent claims that should be adjudicated, but it is logical and efficient to coordinate those claims with the claims and counterclaims in Arbutus's New Jersey Action.

## THE SCIENTIFIC CONTEXT

9. Traditional vaccines create immunity by injecting a patient with pieces of the virus, or an inactive form of that virus. The vaccines that Acuitas helped to develop utilize messenger RNA ("mRNA") technology, do not require injection of the virus, and were developed much more quickly than traditional vaccines. All living organisms, including both humans and viruses, make proteins, which are the workhorses that complete the tasks needed by that organism. In humans the "blueprint" for these proteins is carried in genes (i.e., DNA), but that blueprint needs to be converted into an mRNA message that tells the body to make a particular protein.

10. mRNA vaccines work by introducing into a person the mRNA message that instructs the body to make a foreign protein that is itself a piece of a virus. When that viral protein is made, or "expressed," by the person's cells, that person's immune system then recognizes that the protein is foreign and develops an immune response to it. If that person is later infected with

the virus itself, his or her immune system is primed to protect against or minimize the significance of the viral infection. Because the mRNA contained in the vaccine represents a protein that is only a piece of the virus, the entire virus is never introduced into the body and there is thus no risk of infection from the vaccine.

11. For all of its advantages, however, working with mRNA presents prodigious challenges. First, mRNA is exceptionally fragile and, when injected into the body, breaks down extremely quickly. Second, mRNA is too large a molecule to enter into human cells on its own. An mRNA vaccine therefore requires a delivery system that protects the mRNA after it is injected into the person and transports the mRNA into the person's cells.

12. In the decade before COVID-19 emerged, Acuitas worked to solve that delivery-system problem: it painstakingly engineered a microscopic sphere of fats called a Lipid Nanoparticle, or "LNP," that can envelop and protect the mRNA. These mRNA-LNPs protect the fragile mRNA, allow it to cross the membrane of a human cell, and then release the mRNA so that it can be used to create the proteins that will in turn generate an immune response. One of Acuitas's mRNA-LNPs is used, under license, in Pfizer and BioNTech's COVID-19 vaccine, COMIRNATY®, which has been a global success in protecting people from COVID-19. To date, over 350 million doses of COMIRNATY® have been administered in the United States.

13. Arbutus and Genevant had nothing to do with that success. Neither has a COVID-19 vaccine, neither has created any component of such a vaccine, and neither has commercialized an LNP that can effectively wrap and protect any mRNA molecule. On the contrary, only after COMIRNATY® achieved worldwide commercial success did Arbutus and Genevant emerge to make the spurious claim, in threat letters and a lawsuit in this District, that COMIRNATY® infringes Arbutus's patents, and, on information and belief, to seek hundreds of millions, if not

billions, of dollars in wholly unjustified payments. Arbutus and Genevant seek the benefits flowing from COMIRNATY® without having borne any of the burden of developing it. Their claim to rights in—and payment for—COMIRNATY® is baseless.

14. What is now Arbutus was originally founded as Inex Pharmaceuticals Inc. in the early 1990s, by leading LNP scientists Dr. Pieter Cullis, Dr. Thomas Madden, and Dr. Michael Hope, to develop therapeutics incorporating lipid-based nanomaterials. This research led to the development of anticancer therapeutics that provided greater potency in fighting tumors while reducing the side effects often seen with such drugs. Subsequently, Inex (later known as Tekmira Pharmaceuticals Corp.) developed LNPs to deliver new classes of drugs based on a type of nucleic acid called small interfering RNA, or "siRNA," which are short pieces of RNA that interfere with the body's ability to make certain proteins that may cause disease. Some of this research led to the development of an siRNA therapeutic called ONPATTRO®.

15. By 2008 the company that is now Arbutus was no longer interested in supporting the work that Dr. Madden and Dr. Hope were pursuing, and terminated their employment. Together with Dr. Cullis, Drs. Madden and Hope founded Acuitas Therapeutics Inc. (originally called AlCana Technologies Inc.) to develop LNP technology, and, by 2012, Acuitas had decided to focus on the development of LNP technology for the delivery of mRNA. Conversely, Arbutus chose to focus its business on the much less challenging problem of developing LNP carriers to encapsulate siRNA.

16. There were good scientific reasons for Arbutus to have bet on siRNA therapeutics rather than mRNA therapeutics. Despite the similarity in their names, siRNA and mRNA are fundamentally different in ways that may frustrate the design of LNPs to encapsulate mRNA. For starters, there is the size difference: mRNA molecules are much larger than siRNA molecules,

with the mRNA in COMIRNATY® some 200 times longer than an average siRNA molecule. Then there is the rigidity difference: siRNA molecules are akin to short, sturdy rods, while the longer mRNA molecules can fold and wind into complex shapes. The technology needed to wrap an siRNA molecule in a lipid nanoparticle is thus vastly different (and simpler) than what is needed to wrap an mRNA molecule. Importantly, mRNA is also much less stable than siRNA, significantly complicating mRNA's formulation and encapsulation in LNP and the manufacture of mRNA vaccines.

17. While the hope for an mRNA therapeutic is over thirty years old, mRNA's inherent instability and its inability to enter cells presented major barriers to its clinical use. In addition, previously known ways to package and deliver mRNA were either ineffective or toxic.

18. Acuitas's scientists—including Drs. Madden, Cullis, and Hope, who have been working on lipids and LNP formulations for drug delivery for decades—solved those problems. Acuitas's research focused on the design and synthesis of novel lipids that provide more efficient and safe delivery of mRNA. They identified appropriate formulation conditions to allow efficient encapsulation of mRNA into LNPs and, importantly, to protect the mRNA from degradation during the formulation process. Acuitas's research involved analytical, biophysical, and preclinical characterization of lipid and lipid component properties to guide lipid and LNP development and to ensure they have the most advantageous safety and efficacy profiles. Acuitas elucidated the mechanism by which mRNA-LNPs are taken up by cells. Acuitas also conducted biophysical analyses of novel mRNA-LNPs and determined which structural and biophysical properties of the LNP components are critical for activity and safety. This research resulted in the identification of hundreds of novel lipids with improved activity and safety. Acuitas tested hundreds of different LNPs with mRNA in order to determine the characteristics for successful

encapsulation. And Acuitas's scientists, in collaborations with its partners, evaluated different LNPs for use in a variety of different vaccines, including COMIRNATY®. This research was published in leading scientific journals, including in *Nature*.

19. Acuitas partners with companies who are developing or seeking to develop therapeutics, including vaccines targeting COVID-19 and other viruses, to address unmet clinical needs. This work, and the potential benefit of the Acuitas mRNA-LNP technology, goes far beyond a vaccine against the virus that causes COVID-19. Acuitas also patented its novel discoveries, which include the ionizable cationic lipid known as ALC-0315, which is used in the LNP in COMIRNATY®.

20. Acuitas and its researchers received global praise, recognition, and awards for their role in developing the LNP technology required for mRNA vaccines, including the critical LNP component of COMIRNATY®. These awards include the 2021 Global Impact Award by Life Sciences British Columbia, the Prince Mahidol Award, the VinFuture Grand Prize, the BIAL Award in Biomedicine, and the admission of Dr. Pieter Cullis to the Order of Canada.

## DEVELOPMENT OF COMIRNATY®

21. The origins of COMIRNATY® lie in collaborations between Acuitas and BioNTech that preceded the COVID-19 pandemic. In 2017, Acuitas and BioNTech began to collaborate on the development of mRNA therapeutic products using the Acuitas LNP technology. At or around the same time, Acuitas had also been collaborating with another German company, CureVac N.V. ("CureVac"), which in 2019 began a Phase 1 clinical trial of an mRNA vaccine against rabies, using Acuitas's LNP technology. In January 2020, CureVac released the results of this clinical trial, showing a strong immune response to the vaccine at a remarkably low dose. These very encouraging clinical data were released at the same time as the global threat from

COVID-19 was becoming apparent. Acuitas therefore quickly engaged with CureVac and BioNTech to discuss use of the same LNP technology to develop an mRNA vaccine against COVID-19. The LNP used in the rabies vaccine contained the proprietary Acuitas lipids ALC-315 and ALC-159, and Acuitas recommended that the planned COVID-19 vaccine use the same LNP composition.

22. The development of COMIRNATY® itself began in January 2020, at the onset of the pandemic, when BioNTech started creating an mRNA molecule that codes for the "spike protein" of the COVID-19 SARS-CoV-2 coronavirus. BioNTech began working with Pfizer in March 2020 to develop and produce a COVID-19 vaccine. The rapid development of COMIRNATY® was possible in part because BioNTech had access to the Acuitas LNP technology, and had been collaborating with Acuitas on the use of that technology for several years. Further, Acuitas actively supported the formulation and evaluation of various COVID-19 vaccine candidates and worked with BioNTech and Pfizer to support scale-up of the manufacturing process to allow subsequent production of the billions of vaccine doses needed globally.

23. Clinical trials of COMIRNATY® began in late April of 2020, with preliminary Phase 3 results demonstrating their safety and efficacy published in just over six months.

24. While clinical trials were ongoing, the federal government recognized the importance of the vaccine and announced a $1.95 billion contract to purchase 100 million doses of COMIRNATY® in July of 2020 and announced another $1.95 billion contract for another 100 million doses of COMIRNATY® by December 2020, bringing the government's total purchase commitment to almost $4 billion.

25. By November 9, 2020, it had been publicly reported that Acuitas had partnered with BioNTech, and that Acuitas's lipids and LNPs were used in Pfizer and BioNTech's COMIRNATY® vaccine.

26. On November 18, 2020, BioNTech and Pfizer announced that their COVID-19 vaccine met all the primary efficacy endpoints in their Phase three study, demonstrating an efficacy rate of 95% ($p < 0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), as measured from seven days after the second dose of the vaccine.

27. On November 20, 2020, based on very high interim vaccine-efficacy results in a Phase 3 clinical study, Pfizer and BioNTech submitted a request for Emergency Use Authorization ("EUA") of COMIRNATY® to the U.S. Food and Drug Administration ("FDA").

28. On December 10, 2020, COMIRNATY® was approved by the FDA under an Emergency Use Authorization to prevent COVID-19 in individuals sixteen years of age and older. That EUA approval came less than ten months after BioNTech first created an mRNA molecule coding for the spike protein of the SARS-CoV-2 virus.

29. COMIRNATY® immediately started being deployed nationwide in vaccination efforts.

30. By summer 2021, the federal government and the European Union had negotiated deals with Pfizer and BioNTech to purchase billions of doses of COMIRNATY®.

31. On May 10, 2021, the FDA expanded the Emergency Use Authorization of COMIRNATY® to include children as young as twelve. Later, on October 29, 2021, the Emergency Use Authorization was expanded to children as young as five.

32. As a result of the safety profile and efficacy of COMIRNATY®, including information obtained as a result of the successful vaccination efforts during 2020 and early 2021, and in conjunction with further scientific studies, the FDA gave full approval of COMIRNATY® on August 23, 2021. COMIRNATY® was the first COVID-19 vaccine to receive such approval.

33. Following full approval, COMIRNATY® was found to be efficacious in combating not just the original COVID-19 strains but also the Beta, Delta, and Omicron variants that swept the world following the initial 2020 outbreak.

34. To date, Pfizer and BioNTech have delivered millions of doses of COMIRNATY® worldwide to combat the COVID-19 pandemic, all containing the lipids and lipid nanoparticles innovated by Acuitas that deliver this critical mRNA therapeutic.

**THE DEFENDANTS' DEMAND LETTERS**

35. When Arbutus saw the tremendous success of the mRNA vaccines for COVID-19, it realized that having chosen to pursue siRNA therapeutics instead of mRNA was a bad decision, both scientifically and financially. On November 23, 2020, just three days after seeing the successful clinical-trial results and recognizing the real possibility that COMIRNATY® would be the first COVID-19 vaccine to be authorized in the United States, Defendants sent a 35 U.S.C. § 287(a) notice, which is a predicate for recovery of damages in a patent-infringement action, to Pfizer, copying Acuitas's licensee and partner BioNTech, threatening to assert eight patents against the sale and use of the COMIRNATY® vaccine. At that time, COMIRNATY® was being evaluated for Emergency Use Authorization by the FDA, so Arbutus and Genevant knew that it would be impossible for Pfizer and BioNTech to consider Arbutus and Genevant's LNP technology in connection with COMIRNATY®. Thus, while Arbutus and Genevant's November 23, 2020 letter included generic language asserting there would be a benefit for Pfizer to partner

with Genevant, the true purpose of the letter—as confirmed by its timing and citation to 35 U.S.C. § 287(a)—was a threat of a patent-infringement suit.

36. The same is true of their second such letter, sent on October 12, 2021, which added a ninth patent that issued on the same day.

37. On June 3, 2022, Defendants sent a third patent-infringement notice letter to BioNTech, copying Pfizer, adding two more newly issued patents.

**ACUITAS'S NEW YORK ACTION AND THIS ACTION**

38. Defendants' 35 U.S.C. § 287(a) patent-infringement notices, their seeking substantial royalties, and the prospect of future claims against other Acuitas licensees seeking to use Acuitas's LNPs for other mRNA vaccines and therapeutics, threaten to cause serious harm to Acuitas's business and expose Acuitas to potential claims of indirect infringement and/or indemnity obligations under its contracts with its customers and partners. Therefore, on March 18, 2022, after Arbutus and Genevant sent their second demand letter, Acuitas filed the New York Action, seeking a declaratory judgment that the nine Arbutus patents, cited in Arbutus and Genevant's November 2020 and October 2021 letters, are not infringed by the manufacture, use, offer for sale, sale, or importation into the United States of COMIRNATY® and are, in any event, invalid.

39. Arbutus and Genevant moved to dismiss the New York Action on October 4, 2022, arguing that there was a lack of substantial controversy and adverse legal interests between Acuitas and them, because Arbutus and Genevant were supposedly just engaging in business collaborations with BioNTech and Pfizer and "[t]here is no need to burden the Court with Acuitas's premature side-show action when the actual parties to the discussions have not sought judicial intervention and a license could moot this case at any time."

40. Despite their "nothing to see here" assurances to the New York court, within six months of these assurances and over a year after Acuitas filed the New York Action, on April 3, 2023, Arbutus and Genevant sued Pfizer and BioNTech in this Court, relying on the same demand letters as a basis for contentions of willfulness and explicitly identifying Acuitas's lipids and LNPs in alleging that COMIRNATY® infringes their patents. On information and belief, Arbutus and Genevant seek hundreds of millions, if not billions, of dollars in royalties on sales of COMIRNATY®. On July 10, 2023, Pfizer and BioNTech filed their answer and counterclaims in Arbutus's New Jersey Action, raising as a defense that Arbutus and Genevant had improperly failed to name or join Acuitas as a "required party."

41. As of the date of this Complaint, Acuitas's New York Action had not progressed past the pleadings stage; Arbutus's and Genevant's motion to dismiss remained pending. In the interest of judicial economy, conservation of parties' resources, and avoidance of inconsistent outcomes, today Acuitas voluntarily, and without prejudice, dismissed its New York Action pursuant to Federal Rule of Civil Procedure 41(a)(1)(A)(i), and is filing this action in this District.

42. Specifically, pursuant to Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201, Acuitas seeks a declaratory judgment that the following ten Arbutus patents—the same patents that were included in Arbutus and Genevant's demand letters and five of the same patents are asserted in Arbutus's New Jersey Action—are not infringed by the manufacture, use, offer for sale, sale, or importation into the United States of COMIRNATY® and are, in any event, invalid: U.S. Patent Nos. 9,364,435 (the "'435 patent"); 8,058,069 (the "'069 patent"); 8,492,359 (the "'359 patent"); 8,822,668 (the "'668 patent"); 9,006,417 (the "'417 patent"); 9,504,651 (the "'651

patent"); 9,518,272 (the "'272 patent"); 11,141,378 (the "'378 patent"); 11,298,320 (the "'320 patent"); 11,318,098 (the "'098 patent") (collectively the "Arbutus Patents").[1]

**THE PARTIES**

43. Plaintiff Acuitas is a leading biotechnology company that collaborates with partner companies and academic institutions to develop new therapies to address unmet clinical needs. It is a Canadian corporation organized and existing in British Columbia, Canada, with a principal place of business at 6190 Agronomy Road, Suite 405, Vancouver, British Columbia, V6T 1Z3, Canada.

44. Acuitas specializes in the development of mRNA-LNP formulations for use as therapeutics. Acuitas has partnered with non-parties BioNTech and Pfizer to supply and license the LNP used in COMIRNATY®, a COVID-19 vaccine being administered to protect people around the world. COMIRNATY® has received full approval for use by the FDA.

45. On information and belief, Defendant Genevant Sciences GmbH, an indirect wholly owned subsidiary of Genevant Sciences Ltd. (itself a Bermuda holding company), is a limited-liability company organized and existing under the laws of Switzerland with a principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland.

46. On information and belief, Defendant Arbutus Biopharma Corp. (variously known in the past as Tekmira, Protiva, and Inex, and referred to herein as "Arbutus") is a corporation organized and existing under the laws of Canada with corporate headquarters at 1066 W. Hastings

[1] Acuitas's New York Action included a count seeking a declaratory judgment that Arbutus's U.S. Patent No. 9,404,127 (the "'127 patent") is invalid and not infringed by COMIRNATY®. Subsequently, however, the United States Court of Appeals for the Federal Circuit affirmed the invalidity of all claims of the '127 patent. *See Arbutus Biopharma Corp. v. ModernaTx, Inc.*, No. 2020-1183, Docket Nos. 94, 95 (Fed. Cir. Apr. 11, 2023). Acuitas is therefore not including the '127 patent in this case.

Street Suite 1600, Vancouver, British Columbia, V6E 3X1, Canada and with research headquarters and principal place of business at 701 Veterans Circle, Warminster, Pennsylvania 18974.

47. Arbutus is the owner of all rights, title and interest to each of the Arbutus Patents. Upon information and belief, Genevant holds a license to each of the Arbutus Patents.

**JURISDICTION AND VENUE**

48. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201.

49. In bringing this action, Acuitas joins a long history of product suppliers who, under circumstances like these, respond to patent-infringement actions against their partners and customers by bringing a declaratory-judgment action against the patentee. Acuitas will demonstrate that the Arbutus Patents are invalid, and also that they are not infringed by COMIRNATY® or by Acuitas's LNP incorporated in COMIRNATY®.

50. Arbutus and Acuitas are competitors in the LNP industry. Arbutus and Genevant are claiming credit for the lipids and LNPs that Acuitas itself invented and licensed. And this is not the first fight between the two companies about the inventorship of LNP technology. In the past there have been two litigations between them involving LNP technology. By agreement reached in 2012, Acuitas and Arbutus spent the last decade pursuing different scientific pathways: Acuitas sought to develop LNPs that could deliver mRNA, while Arbutus sought to develop LNPs for an entirely different kind of nucleic acid called siRNA.

51. Now that Acuitas's LNPs have been used in mRNA vaccines that have helped save the world from a pandemic, Arbutus and Genevant—which have no FDA-approved and on-the-market mRNA and anti-COVID product—have shown up, falsely claiming to have invented that lifesaving technology, and filing patent-infringement lawsuit against BioNTech and Pfizer.

Inherent in these claims is Arbutus and Genevant's belief that Acuitas's LNP used in COMIRNATY® is covered by an element of their patent claims. Indeed, Arbutus's New Jersey Action explicitly identifies Acuitas's lipids and LNPs while alleging that COMIRNATY® infringes their patents. That creates a risk of Acuitas itself facing the possibility of liability under 35 U.S.C. § 271(b) for inducing its customers' infringement or under § 271(c) for contributing to it.

52. On November 23, 2020—the same day that they sent their first 35 U.S.C. § 287(a) notice to Pfizer and BioNTech—Arbutus and Genevant sent a similar patent-infringement notice to the only other company with a COVID-19 mRNA vaccine, Moderna. Arbutus and Genevant then sued Moderna for patent infringement on February 28, 2022, asserting six of the same patents that were the subject of the New York Action and three of the same patents as asserted in the Arbutus's New Jersey Action. Arbutus and Genevant sent two more patent-infringement notices to Pfizer and BioNTech—with the last notice sent on June 3, 2022—and sued Pfizer and BioNTech for patent infringement on April 4, 2023, in this District.

53. Acuitas's license agreement with BioNTech contains indemnification provisions. Citing these provisions, and after receiving patent-infringement notices from Arbutus and Genevant, BioNTech gave notice to Acuitas, in January 2022, August 2022, and May 2023, of a claim for indemnification. Specifically, BioNTech identified the ten patents-in-suit in this action, and asserted that under the license agreement, Acuitas was obligated to indemnify BioNTech for any damages, litigation costs, or other expenses due to actual and threatened patent-infringement lawsuits by Arbutus and Genevant. Whether or not Acuitas ultimately would have indemnification obligations, BioNTech's assertion that it has indemnification rights is sufficient to create

declaratory-judgment jurisdiction to resolve Acuitas's challenges to the asserted patents—particularly when Defendants have sued BioNTech on five of the ten asserted patents.

54. Based on the facts alleged herein, this Court has subject-matter jurisdiction over a declaratory-judgment action by a supplier (here, Acuitas) against a patentee (here, Arbutus and Genevant) that has threatened and sued the supplier's partners, customer, and licensee (here, Pfizer and BioNTech) either (i) where the supplier faces the possibility of liability under 35 U.S.C. § 271(b) for inducing its customers' infringement, or under § 271(c) for contributing to it, or (ii) where the supplier may have to indemnify its customers under their contracts.

55. This Court has personal jurisdiction over Arbutus and Genevant as well. In Arbutus's New Jersey Action, Arbutus and Genevant allege that Pfizer and BioNTech should reasonably have anticipated being sued in New Jersey with respect to COMIRNATY®. Thus, Arbutus and Genevant reasonably anticipated that they might be sued in New Jersey in claims arising out of that same alleged infringement.

56. Moreover, Arbutus and Genevant purposefully availed themselves of the jurisdiction of, and consented to be sued by Acuitas in, this Court by *filing suit here* against Pfizer and BioNTech in a lawsuit that is at least in part about, and that explicitly names, Acuitas's LNPs. The entire theory of the Arbutus's New Jersey Action is that Arbutus and Genevant invented the "LNP technologies needed to deliver messenger ribonucleic acid ('mRNA') therapeutics" used in Pfizer and BioNTech's COMIRNATY®, and that this technology is allegedly "key." Arbutus and Genevant filed Arbutus's New Jersey Action while knowing about, and litigating, Acuitas's New York Action. They should have known, and on information and belief did know, that Acuitas might seek to litigate its claims in this Court rather in New York.

57. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

## THE PATENTS IN SUIT

**U.S. Patent No. 9,364,435**

58. On information and belief, Arbutus is the owner of all rights, title, and interest in the '435 patent, entitled "Lipid Formulations for Nucleic Acid Delivery." The USPTO issued the '435 patent on June 14, 2016. The '435 patent names Edward Yaworski, Kieu Lam, Lloyd Jeffs, Lorne Palmer, and Ian MacLachlan as inventors. All the named inventors assigned the '435 patent to Protiva, which subsequently amalgamated into Arbutus. A copy of the '435 patent is attached to this Complaint as Exhibit A.

59. The '435 patent contains an independent claim, claim 1, that claims a "nucleic acid-lipid particle comprising" "a nucleic acid," "a cationic lipid comprising from 50 mol % to 85 mol % of the total lipid," "a non-cationic lipid," and "a conjugated lipid that inhibits aggregation of particles." Further, the '435 patent claims methods of "introducing a nucleic acid into a cell," "in vivo delivery of a nucleic acid," and "treating a disease or disorder" comprising the nucleic acid-lipid particle claimed in claim 1.

**U.S. Patent No. 8,058,069**

60. On information and belief, Arbutus is the owner of all rights, title, and interest in the '069 patent, entitled "Lipid Formulations for Nucleic Acid Delivery." The United States Patent and Trademark Office issued the '069 patent on November 15, 2011. The '069 patent names Edward Yaworski, Kieu Lam, Lloyd Jeffs, Lorne Palmer, and Ian MacLachlan as inventors. All the named inventors assigned the '069 patent to Protiva, which subsequently amalgamated into Arbutus. A copy of the '069 patent is attached to this Complaint as Exhibit B.

61. The ’069 patent contains one independent claim, claim 1, which claims a “nucleic acid-lipid particle comprising” “a nucleic acid,” “a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid,” “a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof,” and “a conjugated lipid that inhibits aggregation of particles.”

**U.S. Patent No. 8,492,359**

62. On information and belief, Arbutus is the owner of all rights, title, and interest in the ’359 patent, entitled “Lipid Formulations for Nucleic Acid Delivery.” The USPTO issued the ’359 patent on July 23, 2013. The ’359 patent names Edward Yaworski, Kieu Lam, Lloyd Jeffs, Lorne Palmer, and Ian MacLachlan as inventors. All the named inventors assigned the ’359 patent to Protiva, which subsequently amalgamated into Arbutus. A copy of the ’359 patent is attached to this Complaint as Exhibit C.

63. The ’359 patent contains one independent claim, claim 1, which claims a “nucleic acid-lipid particle comprising” “a nucleic acid,” “a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid,” “a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof,” and “a conjugated lipid that inhibits aggregation of particles.”

**U.S. Patent No. 8,822,668**

64. On information and belief, Arbutus is the owner of all rights, title, and interest in the ’668 patent, entitled “Lipid Formulations for Nucleic Acid Delivery.” The USPTO issued the ’668 patent on September 2, 2014. The ’668 patent names Edward Yaworski, Kieu Lam, Lloyd Jeffs, Lorne Palmer, and Ian MacLachlan as inventors. All the named inventors assigned the ’668 patent to Protiva, which subsequently amalgamated into Arbutus. A copy of the ’668 patent is attached to this Complaint as Exhibit D.

65. The ’668 patent contains an independent claim, claim 1, that claims a “nucleic acid-lipid particle comprising” “a nucleic acid,” “a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid,” “a non-cationic lipid . . . comprising a mixture of a phospholipid and cholesterol or a derivative thereof,” and “a conjugated lipid that inhibits aggregation of particles.” Further, the ’668 patent claims methods for “treating a disease or disorder” and “in vivo delivery of a nucleic acid” comprising the administration of the “nucleic acid-lipid particle” of claim 1.

**U.S. Patent No. 9,006,417**

66. On information and belief, Arbutus is the owner of all rights, title, and interest in the ’417 patent, entitled “Non-Liposomal Systems for Nucleic Acid Delivery.” The USPTO issued the ’417 patent on April 14, 2015. The ’417 patent names Edward Yaworski, Lloyd Jeffs, and Lorne Palmer as inventors. All the named inventors assigned the ’417 patent to Protiva, which subsequently amalgamated into Arbutus. A copy of the ’417 patent is attached to this Complaint as Exhibit E.

67. The ’417 patent contains an independent claim, claim 1, that claims a “composition comprising” “plurality of nucleic acid-lipid particles, wherein each particle . . . comprises” “a nucleic acid,” “a cationic lipid comprising from 50 mol % to 85 mol % of the total lipid,” “a non-cationic lipid,” and “a conjugated lipid that inhibits aggregation of particles” where “at least about 95% of the particles . . . have a non-lamellar morphology.” Further, the ’417 patent claims methods of “introducing a therapeutic agent into a cell” and “in vivo delivery of a therapeutic agent” comprising the composition claimed in claim 1.

**U.S. Patent No. 9,504,651**

68. On information and belief, Arbutus is the owner of all rights, title, and interest in the ’651 patent, entitled “Lipid Compositions for Nucleic Acid Delivery.” The USPTO issued the

'651 patent on November 29, 2016. The '651 patent names Ian MacLachlan, Lloyd Jeffs, Lorne Palmer, and Cory Giesbrecht as inventors. All the named inventors assigned the '651 patent to Protiva, which subsequently amalgamated into Arbutus. A copy of the '651 patent is attached to this Complaint as Exhibit F.

69. The '651 patent contains one independent claim, claim 1, which claims a "lipid vesicle formulation comprising" "a plurality of lipid vesicles, wherein each lipid vesicle comprises" "a cationic lipid; an amphipathic lipid; and a polyethyleneglycol (PEG)-lipid" and a "messenger RNA."

**U.S. Patent No. 9,518,272**

70. On information and belief, Arbutus is the owner of all rights, title, and interest in the '272 patent, entitled "Non-Liposomal Systems for Nucleic Acid Delivery." The USPTO issued the '272 patent on December 13, 2016. The '272 patent names Edward Yaworski, Lloyd Jeffs, and Lorne Palmer as inventors. All the named inventors assigned the '272 patent to Protiva, which subsequently amalgamated into Arbutus. A copy of the '272 patent is attached to this Complaint as Exhibit G.

71. The '272 patent contains an independent claim, claim 1, that claims a "composition comprising" "a plurality of nucleic acid-lipid particles, wherein each particle . . . comprises" "a nucleic acid," "a cationic lipid," "a non-cationic lipid," and "a conjugated lipid that inhibits aggregation of particles" where "at least 95% of the particles . . . are electron-dense." Further, the '272 patent claims methods of "introducing a therapeutic agent into a cell" and "in vivo delivery of a therapeutic agent" comprising the composition claimed in claim 1.

**U.S. Patent No. 11,141,378**

72. On information and belief, Arbutus is the owner of all rights, title, and interest in the '378 patent, entitled "Lipid Formulations for Nucleic Acid Delivery." The USPTO issued the '378 patent on October 12, 2021. The '378 patent names Edward Yaworski, Kieu Lam, Lloyd Jeffs, Lorne Palmer, and Ian MacLachlan as inventors. All the named inventors assigned the '378 patent to Arbutus. A copy of the '378 patent is attached to this Complaint as Exhibit H.

73. The '378 patent contains one independent claim, claim 1, which claims a "nucleic acid-lipid particle consisting essentially of" "an RNA," "a cationic lipid having a protonatable tertiary amine," "a mixture of a phospholipid and cholesterol," and "a polyethyleneglycol (PEG)-lipid conjugate."

**U.S. Patent No. 11,298,320**

74. On information and belief, Arbutus is the owner of all rights, title, and interest in the '320 patent, entitled "Liposomal Apparatus and Manufacturing Methods." The USPTO issued the '320 patent on April 12, 2022. The '320 patent names Ian MacLachlan, Lloyd Jeffs, Lorne Palmer, and Cory Giesbrecht as inventors. All the named inventors assigned the '320 patent to Protiva, which subsequently amalgamated into Arbutus. A copy of the '320 patent is attached to this Complaint as Exhibit I.

75. The '320 patent contains two independent claims, claims 1 and 18. Claim 1 claims an apparatus for producing "a lipid vesicle encapsulating a nucleic acid within the lipid vesicle" the apparatus comprising: "a first reservoir containing an aqueous solution including a nucleic acid," "a second reservoir containing an organic lipid solution, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v," and "a pump mechanism configured to pump the aqueous solution and the organic

lipid solution into a mixing chamber at different flow rates relative to each other," "wherein the mixing chamber is configured such that the aqueous solution and the organic lipid solution are introduced into the mixing chamber as opposing flows at about 180° relative to each other and mixed within the mixing chamber to instantaneously produce a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution." Claim 18 claims an apparatus for producing "a lipid vesicle encapsulating a nucleic add [sic] within the lipid vesicle" the apparatus comprising: "a first reservoir containing an aqueous solution including a nucleic acid," "a second reservoir containing an organic lipid solution, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v," and "a pump mechanism configured to pump the aqueous solution and the organic lipid solution into a mixing chamber at different flow rates relative to each other," "wherein the mixing chamber is configured such that the aqueous solution and the organic lipid solution are introduced into the mixing chamber at an angle of between 90° and 180° relative to each other and mixed within the mixing chamber to instantaneously produce a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution."

**U.S. Patent No. 11,318,098**

76. On information and belief, Arbutus is the owner of all rights, title, and interest in the '098 patent, entitled "Liposomal Apparatus and Manufacturing Methods." The USPTO issued the '098 patent on May 3, 2022. The '098 patent names Ian MacLachlan, Lloyd Jeffs, Lorne Palmer, and Cory Giesbrecht as inventors. All the named inventors assigned the '098 patent to Protiva, which subsequently amalgamated into Arbutus. A copy of the '098 patent is attached to this Complaint as Exhibit J.

77. The ’098 patent contains two independent claims, claims 1 and 18. Claim 1 claims a process for producing “a lipid vesicle encapsulating a nucleic acid within the lipid vesicle” the process comprising: “providing an aqueous solution including a nucleic acid in a first reservoir,” “providing an organic lipid solution in a second reservoir, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v,” “introducing the aqueous solution and the organic lipid solution into a mixing chamber as opposing flows at about 180° relative to each other and at different flow rates relative to each other,” and “mixing the organic lipid solution with the aqueous solution, wherein the mixing instantaneously produces a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution.” Claim 18 claims a process for producing “a lipid vesicle encapsulating a nucleic acid within the lipid vesicle” the process comprising: “providing an aqueous solution including a nucleic acid in a first reservoir,” “providing an organic lipid solution in a second reservoir, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v,” “introducing the organic lipid solution and the aqueous solution into a mixing chamber at different flow rates relative to each other and at an angle of between 90° and 180° relative to each other,” and “mixing the organic lipid solution with the aqueous solution, wherein the mixing instantaneously produces a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution.”

**COUNT I**

**(NON-INFRINGEMENT OF THE ’435 PATENT)**

78. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 77.

79. There is an actual controversy between Acuitas and Defendants as to whether the mRNA-LNP formulation in COMIRNATY® meets all the limitations of any valid claim of the '435 patent and whether the manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, infringes any valid claim of the '435 patent.

80. The manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '435 patent.

81. For example, the mRNA-LNP formulation in COMIRNATY® does not comprise "a cationic lipid comprising from 50 mol % to 85 mol % of the total lipid present in the particle" as required by the claims of the '435 patent.

82. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in COMIRNATY® does not meet all of the limitations of any valid claim of the '435 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY®, and the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '435 patent.

**COUNT II**

**(INVALIDITY OF THE '435 PATENT)**

83. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 82.

84. There is an actual controversy between Acuitas and Defendants as to the validity of one or more claims of the '435 patent.

85. The claims of the '435 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 102-103, 112, *et seq*.

86. For example, the claims of the '435 patent are invalid as being anticipated by at least Chen et al., U.S. 2006/0240554 A1 (published Oct. 26, 2006). That was the conclusion of

the Federal Circuit and United States Patent Office in the Final Written Decision in an Inter Partes Review, IPR2018-00739, for certain claims of the '435 patent. In addition, the claims of the '435 patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following prior art: MacLachlan et al., WO 2005/007196 (published Jan. 27, 2005); MacLachlan et al., U.S. Patent Publication No. 2006/0134189 A1 (published June 22, 2006); Lin et al., *Three-Dimensional Imaging of Lipid Gene-Carriers: Membrane Charge Density Controls Universal Transfection Behavior in Lamellar Cationic Liposome-DNA Complexes*, 84 Biophysical J. 3307-16 (2003); Ahmad et al., *New Multivalent Cationic Lipids Reveal Bell Curve for Transfection Efficiency Versus Membrane Charge Density: Lipid-DNA Complexes for Gene Delivery*, 7 J. Gene Med. 739-48 (2005); and Chen et al., U.S. Patent Publication No. 2006/0240554 A1 (published Oct. 26, 2006).

87. The claims of the '435 patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112 because the specification does not describe, or enable a person of ordinary skill in the art to make and use, a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in COMIRNATY®.

88. The claims of the '435 patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention. For example, the specification fails to inform, with reasonable certainty, which lipids constitute a "cationic lipid" within the meaning of the '435 patent and which lipids constitute a "conjugated lipid that inhibits aggregation of particles" within the meaning of the '435 patent.

89. Further, Arbutus argued to the Patent Office, *e.g.*, in IPR2018-00739, IPR2018-00680, and IPR2019-00554, that it is unpredictable whether any given nucleic acid-lipid particle

will be viable when the identity and the amount of the nucleic acid and each of the claimed lipids is changed. For example, Arbutus argued: "The effects of making changes to the proportion of other components in the lipid particle would be unpredictable. Such changes, even if apparently minor in nature, would not be expected to produce a functional lipid particle suitable for systemic use." Patent Owner Response at 18, in IPR2018-00739. Arbutus's arguments confirm that the claims of the '435 patent are invalid for lack of written description, for lack of enablement, and for indefiniteness pursuant to 35 U.S.C. § 112.

90. Acuitas hereby seeks a declaration that the claims of the '435 patent are invalid.

**COUNT III**

**(NON-INFRINGEMENT OF THE '069 PATENT)**

91. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 90.

92. There is an actual controversy between Acuitas and Defendants as to whether the mRNA-LNP formulation in COMIRNATY® meets all the limitations of any valid claim of the '069 patent and whether the manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, infringes any valid claim of the '069 patent.

93. The manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States does not infringe any valid claim of the '069 patent.

94. For example, the mRNA-LNP formulation in COMIRNATY® does not comprise "a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle" as required by the claims of the '069 patent.

95. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in COMIRNATY® does not meet all of the limitations of any valid claim of the '069 patent and that

the manufacture, use, offer to sell, and sale of COMIRNATY®, and the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '069 patent.

**COUNT IV**

**(INVALIDITY OF THE '069 PATENT)**

96. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 95.

97. There is an actual controversy between Acuitas and Defendants as to the validity of any claim of the '069 patent.

98. The claims of the '069 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 102-103, 112, *et seq*.

99. For example, the claims of the '069 patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following prior art to the '069 patent: MacLachlan et al., WO 2005/007196 (published Jan. 27, 2005); MacLachlan et al., U.S. Patent Publication No. 2006/0134189 A1 (published June 22, 2006); Lin et al., *Three-Dimensional Imaging of Lipid Gene-Carriers: Membrane Charge Density Controls Universal Transfection Behavior in Lamellar Cationic Liposome-DNA Complexes*, 84 Biophysical J. 3307-16 (2003); Ahmad et al., *New Multivalent Cationic Lipids Reveal Bell Curve for Transfection Efficiency Versus Membrane Charge Density: Lipid-DNA Complexes for Gene Delivery*, 7 J. Gene Med. 739-48 (2005); and Chen et al., U.S. Patent Publication No. 2006/0240554 A1 (published Oct. 26, 2006).

100. The claims of the '069 patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112 because the specification does not describe, or

enable a person of ordinary skill in the art to make and use, a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in COMIRNATY®.

101. Further, Arbutus argued to the Patent Office, *e.g.*, in IPR2018-00739, IPR2018-00680, and IPR2019-00554, that it is unpredictable whether any given nucleic acid-lipid particle will be viable when the identity and the amount of the nucleic acid and each of the claimed lipids is changed. For example, Arbutus argued: "The effects of making changes to the proportion of other components in the lipid particle would be unpredictable. Such changes, even if apparently minor in nature, would not be expected to produce a functional lipid particle suitable for systemic use." Patent Owner Response at 18, in IPR2018-00739. Such arguments confirm that the claims of the '069 patent are invalid for lack of written description, for lack of enablement, and for indefiniteness pursuant to 35 U.S.C. § 112.

102. The claims of the '069 patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention. For example, the specification fails to inform, with reasonable certainty, which lipids constitute a "cationic lipid" within the meaning of the '069 patent and which lipids constitute a "conjugated lipid that inhibits aggregation of particles" within the meaning of the '069 patent.

103. Acuitas hereby seeks a declaration that the claims of the '069 patent are invalid.

**COUNT V**

**(NON-INFRINGEMENT OF THE '359 PATENT)**

104. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 103.

105. There is an actual controversy between Acuitas and Defendants as to whether the mRNA-LNP formulation in COMIRNATY® meets all the limitations of any valid claim of the '359 patent and whether the manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, infringes any valid claim of the '359 patent.

106. The manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States does not infringe any valid claim of the '359 patent.

107. For example, the mRNA-LNP formulation in COMIRNATY® does not comprise "a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle" as required by the claims of the '359 patent.

108. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in COMIRNATY® does not meet all of the limitations of any valid claim of the '359 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY®, and the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '359 patent.

**COUNT VI**

**(INVALIDITY OF THE '359 PATENT)**

109. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 108.

110. There is an actual controversy between Acuitas and Defendants as to the validity of any claim of the '359 patent.

111. The claims of the '359 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 102-103, 112, *et seq*.

112. For example, the claims of the '359 patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following prior art to the '359 patent: MacLachlan et al., WO 2005/007196 (published Jan. 27, 2005); MacLachlan et al., U.S. Patent Publication No. 2006/0134189 A1 (published June 22, 2006); Lin et al., *Three-Dimensional Imaging of Lipid Gene-Carriers: Membrane Charge Density Controls Universal Transfection Behavior in Lamellar Cationic Liposome-DNA Complexes*, 84 Biophysical J. 3307-16 (2003); Ahmad et al., *New Multivalent Cationic Lipids Reveal Bell Curve for Transfection Efficiency Versus Membrane Charge Density: Lipid-DNA Complexes for Gene Delivery*, 7 J. Gene Med. 739-48 (2005); and Chen et al., U.S. Patent Publication No. 2006/0240554 A1 (published Oct. 26, 2006).

113. The claims of the '359 patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112 because the specification does not describe or enable a person of ordinary skill in the art to make and use a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in COMIRNATY®.

114. Further, Arbutus argued to the Patent Office, *e.g.*, in IPR2018-00739, IPR2018-00680, and IPR2019-00554, that it is unpredictable whether any given nucleic acid-lipid particle will be viable when the identity and the amount of the nucleic acid and each of the claimed lipids is changed. For example, Arbutus argued: "The effects of making changes to the proportion of other components in the lipid particle would be unpredictable. Such changes, even if apparently minor in nature, would not be expected to produce a functional lipid particle suitable for systemic use." Patent Owner Response at 18, in IPR2018-00739. Such arguments confirm that the claims of the '359 patent are invalid for lack of written description, for lack of enablement, and for indefiniteness pursuant to 35 U.S.C. § 112.

115. The claims of the ’359 patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention. For example, the specification fails to inform, with reasonable certainty, which lipids constitute a “cationic lipid” within the meaning of the ’359 patent and which lipids constitute a “conjugated lipid that inhibits aggregation of particles” within the meaning of the ’359 patent.

116. Acuitas hereby seeks a declaration that the claims of the ’359 patent are invalid.

**COUNT VII**

**(NON-INFRINGEMENT OF THE ’668 PATENT)**

117. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 116.

118. There is an actual controversy between Acuitas and Defendants as to whether the mRNA-LNP formulation in COMIRNATY® meets all the limitations of any valid claim of the ’668 patent and whether the manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States infringes any valid claim of the ’668 patent.

119. The manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States does not infringe any valid claim of the ’668 patent.

120. For example, the mRNA-LNP formulation in COMIRNATY® does not comprise “a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle” as required by the claims of the ’668 patent.

121. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in COMIRNATY® does not meet all of the limitations of any valid claim of the ’668 patent and that

the manufacture, use, offer to sell, and sale of COMIRNATY®, and the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '668 patent.

**COUNT VIII**

**(INVALIDITY OF THE '668 PATENT)**

122. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 121.

123. There is an actual controversy between Acuitas and Defendants as to the validity of any claim of the '668 patent.

124. The claims of the '668 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 102-103, 112, *et seq*.

125. For example, the claims of the '668 patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following prior art to the '668 patent: MacLachlan et al., WO 2005/007196 (published Jan. 27, 2005); MacLachlan et al., U.S. Patent Publication No. 2006/0134189 A1 (published June 22, 2006); Lin et al., *Three-Dimensional Imaging of Lipid Gene-Carriers: Membrane Charge Density Controls Universal Transfection Behavior in Lamellar Cationic Liposome-DNA Complexes*, 84 Biophysical J. 3307-16 (2003); Ahmad et al., *New Multivalent Cationic Lipids Reveal Bell Curve for Transfection Efficiency Versus Membrane Charge Density: Lipid-DNA Complexes for Gene Delivery*, 7 J. Gene Med. 739-48 (2005); and Chen et al., U.S. Patent Publication No. 2006/0240554 A1 (published Oct. 26, 2006).

126. The claims of the '668 patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112 because the specification does not describe or

enable a person of ordinary skill in the art to make and use a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in COMIRNATY®.

127. Further, Arbutus argued to the Patent Office, *e.g.*, in IPR2018-00739, IPR2018-00680, and IPR2019-00554, that it is unpredictable whether any given nucleic acid-lipid particle will be viable when the identity and the amount of the nucleic acid and each of the claimed lipids is changed. For example, Arbutus argued: "The effects of making changes to the proportion of other components in the lipid particle would be unpredictable. Such changes, even if apparently minor in nature, would not be expected to produce a functional lipid particle suitable for systemic use." Patent Owner Response at 18, in IPR2018-00739. Such arguments confirm that the claims of the '668 patent are invalid for lack of written description, for lack of enablement, and for indefiniteness pursuant to 35 U.S.C. § 112.

128. The claims of the '668 patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention. For example, the specification fails to inform, with reasonable certainty, which lipids constitute a "cationic lipid" within the meaning of the '668 patent and which lipids constitute a "conjugated lipid that inhibits aggregation of particles" within the meaning of the '668 patent.

129. Acuitas hereby seeks a declaration that the claims of the '668 patent are invalid.

**COUNT IX**

**(NON-INFRINGEMENT OF THE '417 PATENT)**

130. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 129.

131. There is an actual controversy between Acuitas and Defendants as to whether the mRNA-LNP formulation in COMIRNATY® meets all the limitations of any valid claim of the '417 patent and whether the manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States infringes any valid claim of the '417 patent.

132. The manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '417 patent.

133. For example, the mRNA-LNP formulation in COMIRNATY® does not comprise "a cationic lipid comprising from 50 mol % to 85 mol % of the total lipid present in the particle" as required by the claims of the '417 patent.

134. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in COMIRNATY® does not meet all of the limitations of any valid claim of the '417 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY®, and the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '417 patent.

**COUNT X**

**(INVALIDITY OF THE '417 PATENT)**

135. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 134.

136. There is an actual controversy between Acuitas and Defendants as to the validity of any claim of the '417 patent.

137. The claims of the '417 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 102-103, 112, *et seq*.

138. For example, the claims of the '417 patent are invalid as being anticipated under 35 U.S.C. § 102 by at least the '069 patent as set forth in the Final Written Decision in IPR2018-00680. In addition, the claims of the '417 patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following prior art to the '417 patent: the '069 patent; MacLachlan et al., WO 2005/007196 (published Jan. 27, 2005); MacLachlan et al., U.S. Patent Publication No. 2006/0134189 A1 (published June 22, 2006); Lin et al., *Three-Dimensional Imaging of Lipid Gene-Carriers: Membrane Charge Density Controls Universal Transfection Behavior in Lamellar Cationic Liposome-DNA Complexes*, 84 Biophysical J. 3307-16 (2003); Ahmad et al., *New Multivalent Cationic Lipids Reveal Bell Curve for Transfection Efficiency Versus Membrane Charge Density: Lipid-DNA Complexes for Gene Delivery*, 7 J. Gene Med. 739-48 (2005); MacLachlan et al., WO 2009/082817 (published July 9, 2009); and Chen et al., U.S. Patent Publication No. 2006/0240554 A1 (published Oct. 26, 2006).

139. The claims of the '417 patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112 because the specification does not describe or enable a person of ordinary skill in the art to make and use a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in COMIRNATY®.

140. Further, Arbutus argued to the Patent Office, *e.g.*, in IPR2018-00739, IPR2018-00680, and IPR2019-00554, that it is unpredictable whether any given nucleic acid-lipid particle will be viable or have a non-lamellar morphology when the identity and the amount of the nucleic acid and each of the claimed lipids is changed. For example, Arbutus argued: "The effects of making changes to the proportion of other components in the lipid particle would be unpredictable. Such changes, even if apparently minor in nature, would not be expected to produce a functional lipid particle suitable for systemic use." Patent Owner Response at 18, in IPR2018-00739. Such

arguments confirm that the claims of the '417 patent are invalid for lack of written description, for lack of enablement, and for indefiniteness pursuant to 35 U.S.C. § 112.

141. The claims of the '417 patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention. For example, the specification fails to inform, with reasonable certainty, which lipids constitute a "cationic lipid" within the meaning of the '417 patent and which lipids constitute a "conjugated lipid that inhibits aggregation of particles" within the meaning of the '417 patent.

142. Acuitas hereby seeks a declaration that the claims of the '417 patent are invalid.

**COUNT XI**

**(NON-INFRINGEMENT OF THE '651 PATENT)**

143. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 142.

144. There is an actual controversy between Acuitas and Defendants as to whether the mRNA-LNP formulation in COMIRNATY® meets all the limitations of any valid claim of the '651 patent and whether the manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States infringes any valid claim of the '651 patent.

145. The manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '651 patent.

146. For example, the mRNA-LNP formulation in COMIRNATY® does not comprise "a cationic lipid" as required by the claims of the '651 patent.

147. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in COMIRNATY® does not meet all of the limitations of any valid claim of the '651 patent and that

the manufacture, use, offer to sell, and sale of COMIRNATY®, and the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '651 patent.

**COUNT XII**

**(INVALIDITY OF THE '651 PATENT)**

148. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 147.

149. There is an actual controversy between Acuitas and Defendants as to the validity of any claim of the '651 patent.

150. The claims of the '651 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 102-103, 112, *et seq*.

151. For example, the claims of the '651 patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following prior art to the '651 patent: Saravolac et al., U.S. Patent No. 6,734,171 (published May 11, 2004), Semple et al., WO 1998/051278 (published Nov. 19, 1998), and Semple et al., *Efficient Encapsulation of Antisense Oligonucleotides in Lipid Vesicles Using Ionizable Aminolipids: Formation of Novel Small Multilamellar Vesicle Structures*, 1510 Biochimica et Biophysica Acta 152 (2001).

152. The claims of the '651 patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112 because the specification does not describe or enable a person of ordinary skill in the art to make and use a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in COMIRNATY®.

153. Further, Arbutus argued to the Patent Office, *e.g.*, in IPR2018-00739, IPR2018-00680, and IPR2019-00554, that it is unpredictable whether any given lipid vesicle will be viable

or fully encapsulate at least 70% of the mRNA in the formulation when the identity and the amount of mRNA and each of the claimed lipids is changed. For example, Arbutus argued: "The effects of making changes to the proportion of other components in the lipid particle would be unpredictable. Such changes, even if apparently minor in nature, would not be expected to produce a functional lipid particle suitable for systemic use." Patent Owner Response at 18, in IPR2018-00739. Such arguments confirm that the claims of the '651 patent are invalid for lack of written description, for lack of enablement, and for indefiniteness pursuant to 35 U.S.C. § 112.

154. The claims of the '651 patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention. For example, the specification fails to inform, with reasonable certainty, which lipids constitute a "cationic lipid" within the meaning of the '651 patent.

155. Acuitas hereby seeks a declaration that the claims of the '651 patent are invalid.

**COUNT XIII**

**(NON-INFRINGEMENT OF THE '272 PATENT)**

156. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 155.

157. There is an actual controversy between Acuitas and Defendants as to whether the mRNA-LNP formulation in COMIRNATY® meets all the limitations of any valid claim of the '272 patent and whether the manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, infringes any valid claim of the '272 patent.

158. The manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '272 patent.

159. For example, the mRNA-LNP formulation in COMIRNATY® does not comprise "nucleic-acid lipid particles" that comprise "a cationic lipid" as those terms are used in the claims of the '272 patent.

160. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in COMIRNATY® does not meet all of the limitations of any valid claim of the '272 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY®, and the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '272 patent.

**COUNT XIV**

**(INVALIDITY OF THE '272 PATENT)**

161. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 160.

162. There is an actual controversy between Acuitas and Defendants as to the validity of any claim of the '272 patent.

163. The claims of the '272 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 102-103, 112, *et seq*.

164. For example, the claims of the '272 patent are invalid as being anticipated under 35 U.S.C. § 102 by at least the '069 patent for the same reasons as set forth in the Final Decision by the Federal Circuit and Final Written Decision in IPR2018-00680 involving the '127 patent. In addition, the claims of the '272 patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following prior art to the '272 patent: the '069 patent; MacLachlan et al., WO 2005/007196 (published Jan. 27, 2005); MacLachlan et al., U.S. Patent Publication No. 2006/0134189 A1 (published June 22, 2006); Lin et al., *Three-Dimensional*

*Imaging of Lipid Gene-Carriers: Membrane Charge Density Controls Universal Transfection Behavior in Lamellar Cationic Liposome-DNA Complexes*, 84 Biophysical J. 3307-16 (2003); Ahmad et al., *New Multivalent Cationic Lipids Reveal Bell Curve for Transfection Efficiency Versus Membrane Charge Density: Lipid-DNA Complexes for Gene Delivery*, 7 J. Gene Med. 739-48 (2005); MacLachlan et al., WO 2009/082817 (published July 9, 2009); and Chen et al., U.S. Patent Publication No. 2006/0240554 A1 (published Oct. 26, 2006).

165. The claims of the '272 patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112 because the specification does not describe or enable a person of ordinary skill in the art to make and use a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in COMIRNATY®.

166. Further, Arbutus argued to the Patent Office, *e.g.*, in IPR2018-00739, IPR2018-00680, and IPR2019-00554, that it is unpredictable whether any given nucleic acid-lipid particle will be viable or be electron-dense when the identity and the amount of the nucleic acid and each of the claimed lipids is changed. For example, Arbutus argued: "The effects of making changes to the proportion of other components in the lipid particle would be unpredictable. Such changes, even if apparently minor in nature, would not be expected to produce a functional lipid particle suitable for systemic use." Patent Owner Response at 18, in IPR2018-00739. Such arguments confirm that the claims of the '272 patent are invalid for lack of written description, for lack of enablement, and for indefiniteness pursuant to 35 U.S.C. § 112.

167. The claims of the '272 patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention. For example, the specification fails to inform, with reasonable certainty, which lipids constitute a "cationic lipid" within the meaning of the '272 patent and which

lipids constitute a "conjugated lipid that inhibits aggregation of particles" within the meaning of the '272 patent.

168. Acuitas hereby seeks a declaration that the claims of the '272 patent are invalid.

**COUNT XV**

**(NON-INFRINGEMENT OF THE '378 PATENT)**

169. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 168.

170. There is an actual controversy between Acuitas and Defendants as to whether the mRNA-LNP formulation in COMIRNATY® meets all the limitations of any valid claim of the '378 patent and whether the manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, infringes any valid claim of the '378 patent.

171. The manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '378 patent.

172. For example, the mRNA-LNP formulation in COMIRNATY® does not "consist[] essentially of" the claimed components, including "a cationic lipid having a protonatable tertiary amine," as required by the claims of the '378 patent.

173. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in COMIRNATY® does not meet all of the limitations of any valid claim of the '378 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY®, and the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '378 patent.

**COUNT XVI**

**(INVALIDITY OF THE '378 PATENT)**

174. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 173.

175. There is an actual controversy between Acuitas and Defendants as to the validity of any claim of the '378 patent.

176. The claims of the '378 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 102-103, 112, *et seq*.

177. For example, the claims of the '378 patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following prior art to the '378 patent: MacLachlan et al., WO 2005/007196 (published Jan. 27, 2005); MacLachlan et al., U.S. Patent Publication No. 2006/0134189 A1 (published June 22, 2006); Lin et al., *Three-Dimensional Imaging of Lipid Gene-Carriers: Membrane Charge Density Controls Universal Transfection Behavior in Lamellar Cationic Liposome-DNA Complexes*, 84 Biophysical J. 3307-16 (2003); Ahmad et al., *New Multivalent Cationic Lipids Reveal Bell Curve for Transfection Efficiency Versus Membrane Charge Density: Lipid-DNA Complexes for Gene Delivery*, 7 J. Gene Med. 739-48 (2005); and Chen et al., U.S. Patent Publication No. 2006/0240554 A1 (published Oct. 26, 2006).

178. The claims of the '378 patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112 because the specification does not describe or enable a person of ordinary skill in the art to make and use a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in COMIRNATY®.

179. Further, Arbutus argued to the Patent Office, *e.g.*, in IPR2018-00739, IPR2018-00680, and IPR2019-00554, that it is unpredictable whether any given nucleic acid-lipid particle will be viable when the identity and the amount of the RNA and each of the claimed lipids is changed. For example, Arbutus argued: "The effects of making changes to the proportion of other components in the lipid particle would be unpredictable. Such changes, even if apparently minor in nature, would not be expected to produce a functional lipid particle suitable for systemic use." Patent Owner Response at 18, in IPR2018-00739. Such arguments confirm that the claims of the '378 patent are invalid for lack of written description, for lack of enablement, and for indefiniteness pursuant to 35 U.S.C. § 112.

180. The claims of the '378 patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention. For example, the specification fails to inform, with reasonable certainty, which lipids constitute a "cationic lipid having a protonatable tertiary amine" within the meaning of the '378 patent.

181. Acuitas hereby seeks a declaration that the claims of the '378 patent are invalid.

**COUNT XVII**

**(NON-INFRINGEMENT OF THE '320 PATENT)**

182. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 181.

183. There is an actual controversy between Acuitas and Defendants as to whether the apparatus for producing the mRNA-LNP formulation in COMIRNATY® meets all the limitations of any valid claim of the '320 patent and whether the manufacture, use, offer to sell, or sale of

COMIRNATY®, or the importation of COMIRNATY® into the United States infringes any valid claim of the '320 patent.

184. The manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '320 patent. For example, the mRNA-LNP formulation in COMIRNATY® does not comprise "a cationic lipid" as required by the claims of the '320 patent.

185. Acuitas hereby seeks a declaration that the apparatus for producing the mRNA-LNP formulation in COMIRNATY® does not meet all of the limitations of any valid claim of the '320 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY®, and the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '320 patent.

**COUNT XVIII**

**(INVALIDITY OF THE '320 PATENT)**

186. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 185.

187. There is an actual controversy between Acuitas and Defendants as to the validity of any claim of the '320 patent.

188. The claims of the '320 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 102-103, 112, *et seq*.

189. For example, the claims of the '320 patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following prior art to the '320 patent: Quake et al., WIPO Patent Publication No. 2002/040874 (published May 23, 2002),

Semple et al., WO 1998/051278 (published Nov. 19, 1998), and Semple et al., *Efficient Encapsulation of Antisense Oligonucleotides in Lipid Vesicles Using Ionizable Aminolipids: Formation of Novel Small Multilamellar Vesicle Structures*, 1510 Biochimica et Biophysica Acta 152 (2001).

190. The claims of the '320 patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112 because the specification does not describe or enable a person of ordinary skill in the art to make and use a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in COMIRNATY®.

191. Further, Arbutus argued to the Patent Office, *e.g.*, in IPR2018-00739, IPR2018-00680, and IPR2019-00554, that it is unpredictable whether any given lipid vesicle will be viable or encapsulate mRNA in the formulation when the identity and the amount of mRNA and lipids is changed. For example, Arbutus argued: "The effects of making changes to the proportion of other components in the lipid particle would be unpredictable. Such changes, even if apparently minor in nature, would not be expected to produce a functional lipid particle suitable for systemic use." Patent Owner Response at 18, in IPR2018-00739. Such arguments confirm that the claims of the '320 patent are invalid for lack of written description, for lack of enablement, and for indefiniteness pursuant to 35 U.S.C. § 112.

192. The claims of the '320 patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention. For example, the specification fails to inform, with reasonable certainty, what "lower alkanol[s]," "flow rates," and "cationic lipid[s]" fall within the meaning of the '320 patent.

193. Acuitas hereby seeks a declaration that the claims of the '320 patent are invalid.

**COUNT XIX**

**(NON-INFRINGEMENT OF THE '098 PATENT)**

194. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 193.

195. There is an actual controversy between Acuitas and Defendants as to whether the process for producing the mRNA-LNP formulation in COMIRNATY® meets all the limitations of any valid claim of the '098 patent and whether the manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States infringes any valid claim of the '098 patent.

196. The manufacture, use, offer to sell, or sale of COMIRNATY®, or the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '098 patent. For example, the mRNA-LNP formulation in COMIRNATY® does not comprise "a cationic lipid" as required by the claims of the '098 patent.

197. Acuitas hereby seeks a declaration that the apparatus for producing mRNA-LNP formulation in COMIRNATY® does not meet all of the limitations of any valid claim of the '098 patent and that the manufacture, use, offer to sell, and sale of COMIRNATY®, and the importation of COMIRNATY® into the United States, does not infringe any valid claim of the '098 patent.

**COUNT XX**

**(INVALIDITY OF THE '098 PATENT)**

198. Acuitas incorporates by reference herein all of the allegations of paragraphs 1 to 197.

199. There is an actual controversy between Acuitas and Defendants as to the validity of any claim of the '098 patent.

200. The claims of the ’098 patent fail to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 102-103, 112, *et seq*.

201. For example, the claims of the ’098 patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following prior art to the ’320 patent: Quake et al., WIPO Patent Publication No. 2002/040874 (published May 23, 2002), Semple et al., WO 1998/051278 (published Nov. 19, 1998), and Semple et al., *Efficient Encapsulation of Antisense Oligonucleotides in Lipid Vesicles Using Ionizable Aminolipids: Formation of Novel Small Multilamellar Vesicle Structures*, 1510 Biochimica et Biophysica Acta 152 (2001).

202. The claims of the ’098 patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112 because the specification does not describe or enable a person of ordinary skill in the art to make and use a formulation like Acuitas’s mRNA-LNP formulations, including the mRNA-LNP formulation in COMIRNATY®.

203. Further, Arbutus argued to the Patent Office, *e.g.*, in IPR2018-00739, IPR2018-00680, and IPR2019-00554, that it is unpredictable whether any given lipid vesicle will be viable or encapsulate mRNA in the formulation when the identity and the amount of mRNA and lipids is changed. For example, Arbutus argued: “The effects of making changes to the proportion of other components in the lipid particle would be unpredictable. Such changes, even if apparently minor in nature, would not be expected to produce a functional lipid particle suitable for systemic use.” Patent Owner Response at 18, in IPR2018-00739. Such arguments confirm that the claims of the ’098 patent are invalid for lack of written description, for lack of enablement, and for indefiniteness pursuant to 35 U.S.C. § 112.

204. The claims of the '098 patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention. For example, the specification fails to inform, with reasonable certainty, what "lower alkanol[s]," "flow rates," and "cationic lipid[s]" fall within the meaning of the '098 patent.

205. Acuitas hereby seeks a declaration that the claims of the '098 patent are invalid.

**PRAYER FOR RELIEF**

WHEREFORE, Acuitas respectfully requests that this Court enter judgment in favor of Acuitas against Arbutus and Genevant and grant the following relief:

A. Judgment be entered declaring that the manufacture, use, offer to sell, and sale of COMIRNATY® in the United States, and the importation of COMIRNATY® into the United States, does not infringe any valid claims of any of the Arbutus Patents;

B. Judgment be entered declaring that all the claims of each of the Arbutus Patents are invalid;

C. Judgment be entered declaring this is an exceptional case and awarding Acuitas its attorneys' fees pursuant to 35 U.S.C. § 285;

D. Costs and expenses in this action; and

E. Such other and further relief as this Court may deem just and proper.

**JURY DEMAND**

Acuitas, by and through undersigned counsel, hereby demands, pursuant to Federal Rule of Civil Procedure 38, a trial by jury on all claims so triable in this action.

Dated: August 4, 2023

Respectfully submitted,

MARINO, TORTORELLA & BOYLE, P.C.

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**Pro hac vice applications forthcoming*

**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1**

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Plaintiff certifies that this action seeks declaratory relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: August 4, 2023

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**LOCAL CIVIL RULE 11.2 AND 40.1 CERTIFICATION**

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Acuitas states as follows:

Defendants Arbutus Biopharma Corp. and Genevant Sciences GmbH are involved in a proceeding before the U.S. District Court for New Jersey, captioned *Arbutus Biopharma Corp. et al v. Pfizer Inc. et al.*, No. 2:23-cv-01876-ZNQ (D.N.J.), relating in part to the infringement and validity of U.S. Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098. The validity and infringement of those same patents is also at issue in this action.

Defendants Arbutus Biopharma Corp. and Genevant Sciences GmbH are also involved in a proceeding before the U.S. District Court for the District of Delaware, captioned *Arbutus Biopharma Corp. et al. v. Moderna, Inc. et al.*, No. 22-252 (D. Del.), relating in part to the infringement and validity of U.S. Patent Nos. 8,058,069; 8,492,359; 8,822,668; 9,504,651; 9,364,435 and 11,141,378. The validity and infringement of those same patents is also at issue in this action.

Except for the foregoing, the matter in controversy in this action is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: August 4, 2023

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